UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte VLADIMIR KOZLOV and IRENA TSYRLOVA

Appeal No. 2005-0548
Application No. 09/839,164

ON BRIEF

Before ELLIS, ADAMS and GRIMES, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal pursuant to 35 U.S.C. § 134 from the examiner's final rejection of claims 30-32, all the claims pending in the application. Claims 1-29 have been canceled.

As a preliminary matter we note the appellants' statement on page 2 of the Brief, that the claims stand or fall together. Accordingly, for purposes of this appeal, we will consider the issues as they apply to representative claim 30, which reads as follows:

> 30. A pharmaceutical composition consisting essentially of the alpha globin chain of hemoglobin in a pharmaceutically acceptable carrier, wherein the composition is suitable for subcutaneous administration and said alpha globin chain is present in an amount of 0.1 mg to 6 g.

The references relied upon by the examiner are:

Hoffman et al. (Hoffman) 5,449,759 Sep. 12, 1995

Tame et al. (Tame), "Functional Role of the Distal Valine (E11) Residue of α Subunits in Human Haemoglobin," J. Mol. Biol., vol. 218, pp. 761-767 (1991).

The claims stand rejected as follows:

I. Claims 30-32 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Appellants regard as the invention.

II. Claims 30-32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Tame.

III. Claims 30-32 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Hoffman.

We have carefully considered the respective position of the appellants and the examiner and find ourselves in substantial agreement with that of the examiner. Accordingly, we affirm Rejections I, II and III.

Background

The specification points out that

> Most end-stage cells in renewing systems are short-lived and must be replaced continuously throughout life. For example, blood cells originate from a self-renewing population of multipotent hematopoietic stem cells (HSC). Because the hematopoietic stem cells are necessary for the development of all of the mature cells of the hematopoietic and immune systems, their survival is essential in order to reestablish a fully functional host defense system in subjects treated with chemotherapy or other agents [Specification, p. 1, para. 3].

The present invention is said to be directed to compositions which inhibit stem cell proliferation. Specification, p. 2, para. 2. The compositions, which include the alpha chain and the beta chain of hemoglobin, are said to be useful for

> regulating stem cell cycle in the treatment of humans or animals having autoimmune diseases, aging, cancer, myelodysplasia, preleukemia, leukemia, psoriasis or other diseases involving hyperproliferative conditions. The present invention also relates to a method of treatment for humans or animals anticipating or having undergone exposure to chemotherapeutic agents, other agents which damage cycling stem cells or radiation exposure. Finally, the present invention relates to the improvement of stem cell maintenance or expansion cultures for auto and allo-transplantation procedures or for gene transfer [Specification, p. 1, para. 2].

Discussion

Rejection I

The examiner argues that claims 30-32 are indefinite in the recitation of milligram amounts of the alpha chain and beta chain. The examiner contends that "a composition comprises a concentration of a particular item such as grams/liter, for example." Answer, pp. 2-3.

In response, the appellants contend that the claims are not ambiguous, they simply read on a composition in which "0.1 mg to 6 g of alpha and/or beta globin is present regardless of its concentration in the composition." Brief, p. 3.

Analysis of the claims begins with the determination of whether they [the claims] satisfy the requirements of the second paragraph of § 112. In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). In Moore, the court stated:

> . . . the claims must be analyzed first in order to determine exactly what subject matter they encompass. The subject matter there set out must be presumed, in the absence of evidence to the contrary, to be that "which the applicant regards as his invention." (emphasis added).
>
> This first inquiry therefore is merely to determine whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. It is here where the definiteness of the language employed must be analyzed -- not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.

As indicated above, for purposes of this appeal, we will consider the issues only as they apply to representative claim 30.

Here, we agree with the examiner that claim 30 is indefinite in that it is incomplete. As pointed out by the examiner, a claim which is directed to a pharmaceutical composition must include more than simply the mass otherwise one skilled in the art can not ascertain the metes and bounds of said claim. For example, given only the mass as recited in claim 30, one has no way of knowing whether the claimed pharmaceutical composition is a liquid or a solid. That is, even though the claim states that the composition is suitable for subcutaneous administration, it still encompasses a lyophilized alpha globin and pharmaceutically-acceptable carrier which can be reconstituted and administered subcutaneously. If we assume, arguendo, that the appellants intend a pharmaceutical composition which is in a liquid form, lacking a limitation as to the volume as suggested by the examiner (e.g., mg/ml), one skilled in the art cannot determine whether a solution having 0.1 mg alpha globin/ml or 0.1 mg alpha globin/l, for example, constitutes a pharmaceutical composition within the scope of the claim.

Accordingly, in view of the foregoing, we find that the claims "fail to set out and circumscribe a particular area with a reasonable degree of precision and particularity." In re Moore, 439 F.2d at 1235, 169 USPQ at 238. Thus, we affirm Rejection I.

Rejections II and III

The examiner argues that the claimed subject matter is anticipated by the teachings of Tame and Hoffman. The examiner relies on Tame's disclosure of alpha-globin in a buffer solution (i.e., a pharmaceutically acceptable carrier) which was diluted to 0.25 mg/ml (p. 763, col. 1, para. 1). Answer, p. 3. The examiner also points out that Tame discloses the addition of beta globin to the alpha globin solution (p.763, col. 1, para. 1). Id. With respect to the Hoffman patent, the examiner relies on the disclosure of potassium phosphate buffer containing 0.3 mg/ml alpha globin. Id., p. 4. The examiner points out that Hoffman further discloses that a Tris buffer solution containing 5.0 mg/ml of beta globin was added to the alpha globin. Id. The examiner argues that Tame and Hoffman disclose buffer solutions containing 0.1 mg to 6.0 gm of alpha globin, beta globin or alpha globin and beta globin. Id., pp. 3 and 4. Thus, the examiner contends that said solutions anticipate the claimed pharmaceutical compositions.

In response, the appellants argue that because neither Tame nor Hoffman disclose the volume of their solutions, the publications do not describe a solution containing 0.1 mg to 6.0 gm of alpha and/or beta globin. Brief, pp. 4-5. The appellants contend that the examiner is arguing compositions which could be made and, thus, the rejection is based simply on probability or possibility, rather than an actual disclosure. Id., p. 5.

We find these arguments unpersuasive.

Anticipation requires that each and every limitation set forth in a claim be present, either expressly or inherently, in a single prior art reference. In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950 (Fed. Cir. 1999); Celeritas Techs. Ltd v. Rockwell Int'l Corp., 150 F.3d 1354, 1360, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998); Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co., 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984).

As a general rule, having found that the claims are indefinite under § 112, second paragraph, we would not be able reach the issue of whether the claims are patentable over the prior art. In re Steele, 305 F.2d 859 862, 134 USPQ 292, 295 (CCPA 1962) (It is erroneous to analyze claims based on speculation as to the meaning of terms employed and assumptions as to their scope). Here, however, if we accept the appellants' interpretation of representative claim 30 (i.e., that it is directed to a pharmaceutical composition having 0.1 mg to 6 gm of alpha globin regardless of its concentration in the composition (Brief, p. 3)), then we find that said claim is anticipated by the teachings of the applied prior art. That is, contrary to the appellants' argument, we find that Tame discloses a milliliter of buffer containing 5.0 mg of alpha globin. Tame, p. 763, col. 1, para. 2. Tame further discloses a milliliter of buffer containing 0.25 mg of alpha globin. Id. We point out that both alpha globin compositions are within the concentration range set forth in claim 30. In addition, we agree with the

examiner that Hoffman discloses two pharmaceutical compositions consisting essentially alpha globin which are within the scope of the claim; viz., a milliliter of buffer containing 5.0 mg of alpha globin and a milliliter of buffer containing 0.3 gm [sic, 3 mg?] of alpha globin. Thus, since Tame and Hoffman explicitly teach each and every limitation set forth in representative claim 30, we find that the prior art anticipates the appellants' invention.

We have not overlooked the appellants' argument that human alpha globin chains taught by both Tame and Hoffman were produced in E. coli. Brief, p. 6. The appellants contend that the purification procedures disclosed in the applied prior art did not remove endotoxin and, thus, the solutions taught therein would not be suitable for subcutaneous administration to humans. Id. We find this argument to be unconvincing for several reasons.

First, representative claim 30 is not directed to a pharmaceutical composition for use in humans; i.e., no particular species is recited. Accordingly, we find that this argument does not address a limitation present in the claims.

Second, as pointed out by the examiner, the specification discloses that it is advantageous to use a stem cell proliferation inhibitor (INPROL)(e.g., alpha globin) which is produced in a prokaryotic host such as E. coli. Specification, p. 17, para. 1. That is, the specification discloses:

> In an advantageous embodiment, INPROL is the product of prokaryotic or eukaryotic host expression (e.g., bacterial, yeast, higher plant, insect and mammalian cells in culture) of exogenous DNA sequences obtained by genomic or cDNA cloning or by gene synthesis. That is, in an advantageous embodiment

> INPROL is "recombinant INPROL". The product of expression in typical yeast (e.g., Saccharomyces cerevisiae) or prokaryote (e.g., E. coli) host cells are free of association with any mammalian proteins.

Thus, even if we assume, arguendo, that representative claim 30 is limited to use of the pharmaceutical composition in humans, we would find the appellants' argument to be inconsistent with the evidence of record.

Accordingly, in view of the foregoing, the decision of the examiner is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)(1)(iv).

AFFIRMED

JOAN ELLIS
Administrative Patent Judge)

DONALD E. ADAMS
Administrative Patent Judge) BOARD OF PATENT APPEALS AND INTERFERENCES

ERIC GRIMES
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JE/dpv

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